UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **Ethicon Wave I case identified in Exhibit A to Plaintiffs' Motion [Dkt. 2006]**	

MEMORANDUM OF DEFENDANTS IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS IN THE GENERAL REPORT OF TERESA IRWIN, M.D.

Introduction and Summary

Dr. Irwin is a gynecologist with board certifications in Female Pelvic Medicine and Reconstructive Surgery and Obstetrics and Gynecology. She is without question a bona fide expert in the fields of pelvic medicine generally and the surgical treatment of stress urinary incontinence specifically.

Dr. Irwin has issued a general report regarding the TVT medical device and has also issued case-specific reports in three Wave I cases. Plaintiffs in those three cases have not challenged any of Dr. Irwin's case-specific opinions. Likewise, Plaintiffs have not challenged the overwhelming majority of Dr. Irwin's general opinions.

Plaintiffs' motion seeks to limit Dr. Irwin's testimony on only three discreet points: (1) Plaintiffs contend that Dr. Irwin is attempting to offer "design" opinions and that she is not

qualified to do so; (2) Plaintiffs posit that because Dr. Irwin did not review a certain internal Ethicon document she cannot offer her opinions about the lack of clinical significance between fraying/particle loss and complaints of pain; and (3) Plaintiffs argue that Texas evidentiary law prohibits Dr. Irwin from offering the opinion that TVT is "state of the art." None of these arguments has merit.

First, Dr. Irwin does not offer "design" opinions as that term typically connotes. Rather, she discusses the physical characteristics of the various SUI treatment devices and discusses the clinical significance of these characteristics after implant. Her opinions are based upon her clinical practice and her review of the medical literature. Dr. Irwin is imminently qualified to opine regarding how the products -- products that she routinely and regularly implants in her patients – work *in situ*.

Second, Dr. Irwin clearly opines that in her clinical practice and in the medical literature there exists no evidence connecting fraying or particle loss to complaints of pain. Plaintiffs argue that Dr. Irwin should not be allowed to offer this opinion because Ethicon had in its possession a hearsay statement from two surgeons speculating that particle loss may lead to pelvic pain. This is an issue that goes to the weight of Dr. Irwin's testimony, not its admissibility.

Third, Dr. Irwin opines that Ethicon's use of a polypropylene monofilament mesh with pore sizes greater than 75 microns is "state of the art." Plaintiffs argue that Texas evidentiary law prohibits the admissibility of this testimony. This is not a *Daubert* or Rule 702 issue and should be left for a subsequent motion *in limine*. Moreover, Texas law does not prohibit "state of the art" testimony. In fact, Texas law expressly recognizes that "state of the art" evidence is both relevant and admissible.

For these reasons, Plaintiffs' motion to limit Dr. Irwin's testimony should be rejected.

I. ARGUMENT

A. Plaintiffs Tacitly Concede Dr. Irwin Is An Expert Who Should Be Allowed To Testify Regarding All Case-Specific Opinions And The Vast Majority Of Her General Opinions

As an initial matter, it should be noted that Plaintiffs' motion to limit Dr. Irwin's testimony is aimed at three discrete components of her overall opinions. Ethicon designated Dr. Irwin to offer both case-specific and general opinion testimony.

Plaintiffs have not contested *any* of Dr. Irwin's case-specific testimony. This is a tacit concession that Dr. Irwin is qualified to offer all of her case-specific opinion testimony and that her methodology in arriving at her opinions is beyond reproach.

Likewise, Plaintiffs have not contested the overwhelming majority of Dr. Irwin's general opinion testimony. Dr. Irwin's general report spans 56 pages. Plaintiffs' Motion [Dkt. 2006] and Brief [Dkt. 2008] addresses a handful of the paragraphs from her general report. Plaintiffs' silence about the remainder of Dr. Irwin's report concedes the legitimacy of her overarching qualifications and the reliability of her methodology.

B. Dr. Irwin Is Qualified To Offer The Opinions Plaintiffs Dub As "Design" Opinions

Plaintiffs attempt to limit portions of Dr. Irwin's opinion testimony by categorizing them as "design" opinions. Plaintiffs then selectively cherry-pick from Dr. Irwin's deposition to argue that Dr. Irwin admits she is not qualified to offer "design" opinions. Plaintiffs' entire premise for this argument is couched in a fiction of Plaintiffs' own creation: Dr. Irwin never "admitted" that she is unqualified to offer her opinions, and her opinions do not constitute "design" opinions.

1. Plaintiffs falsely claim Dr. Irwin "admitted" to being unqualified

Plaintiffs begin their attack on Dr. Irwin with a barrage of alleged "admissions" from her deposition. Pls.' Br. [Dkt. 2008] at 3-5. While it is true that Dr. Irwin does not hold an

engineering degree and has not personally been involved in the design process of a mesh product, nearly every other alleged "admission" is a misstatement of her testimony. Repeatedly throughout their Brief [Dkt. 2008], Plaintiffs contend that Dr. Irwin "admitted" that she has not "conducted any research" with regard to a multitude of topics and, according to Plaintiffs, this lack of "research" renders Dr. Irwin unqualified to offer her "design" opinions. *See id.*

What Plaintiffs fail to state is that during the deposition, Plaintiffs' counsel defined the term "research" to specifically exclude both literature reviews and Dr. Irwin's clinical experience. *See* Irwin 3/25/16 Dep. Tr. [Dkt. 2006-3] at 36:3-37:4.

> Q. Have you ever done any research concerning the design of pelvic mesh?
>
> A. I've – in terms of the material types and – any part of the design?
>
> Q. Any part of the design.
>
> A. Yes, I've done research on it, yes, sir.
>
> Q. Okay. What research have you done on the design of pelvic mesh?
>
> A. Looking at the literature in terms of the types of mesh types, including the weight and pore size and type of material used.
>
> Q. Let's go – let's – <u>let me define what I mean by "research." I'm not talking about reading and reviewing literature</u>.
>
> A. I understand now.
>
> Q. <u>I'm talking about looking at the specifics of the design of pelvic mesh to determine, you know, okay, we need to do this with it, it needs to have this many – this is how it needs to be knitted, this is what it needs to be made of, this is</u> –
>
> A. Yes, sir, I misunderstood your question. I apologize. I have not.

Id. (emphasis added).

Moreover, Dr. Irwin did not "admit" that she is not an expert in the design of mesh products as Plaintiffs allege. *See* Pls.' Br. [Dkt. 2008] at 3. Rather, she admitted that she has not worked on designing a product but clearly stated that she holds herself out as an expert concerning clinical results obtained from the design of the existing SUI products. *See* Irwin 3/25/16 Dep. Tr. [Dkt. 2006-3] at 35:9-35:15. "I consider myself an expert in pelvic floor surgery and in the material that I use to perform those surgeries, as well as knowing the specifications that are ideal for the pelvic floor cavity." *Id.*

Furthermore, though Plaintiffs continued to espouse their concocted and self-serving definition of the term "research," Dr. Irwin made clear that her expertise is based upon her literature review and clinical experience with the products:

> Q. Okay. Do you consider – do you consider yourself an expert in the pore size of pelvic mesh?
>
> A. I consider myself an expert in knowing what's ideal for the pelvic floor cavity in terms of pore size.
>
> Q. And is that based on your review of literature?
>
> A. Yes, sir.

Id. at 37:9-37:17.

> Q. Okay. Do you consider yourself an expert in the weave of the TVT – of pelvic mesh?
>
> A. I consider myself an expert in terms of the type of materials that I need to use to implant in pelvic floor surgery.
>
> . . .
>
> Q. Outside of your literature review, have you done any research concerning the weave of pelvic mesh?
>
> A. I have not.

Id. at 39:5-39:22 (emphasis added).

Q. . . . Do you consider yourself an expert in the weight or density of pelvic mesh?

A. In terms of knowing what's ideal for the pelvic floor cavity, yes.

. . .

Q. Outside of your literature review for your general opinion – your general report, have you done any research concerning the weight and density of pelvic mesh?

A. No.

. . .

Q. On page 25 to 26 of your report, which is marked as Exhibit 6, you've got information regarding mesh weight or density. Is all that information based solely on your review of medical – review of medical literature?

A. And my experience with patients.

Q. All right. Have you done any testing on weight or density of pelvic mesh?

A. I have not.

Q. Do you consider yourself an expert in the absorption of pelvic mesh?

A. In terms of how it's applied to patients, but not in terms of doing scientific research.

. . .

Q. . . . Have you ever done – outside of your medical literature and your own practice, have you ever done any research into the absorption of pelvic mesh?

A. No.

Id. at 40:5-42:14 (emphasis added).

Q. Are you an expert in biomaterials?

A. I am an expert in terms of implanting these materials in pelvic floor surgery.

> Q. Okay. But are you an expert in how these materials react once they're implanted in the body, the chemical properties of the mesh, et cetera?
>
> A. Clinically.
>
> Q. Outside of your literature review and your own clinical practice, have you ever done any research concerning the biomaterial characteristics of pelvic mesh?
>
> A. No.

Id. at 44:13-45:12 (emphasis added).

At no point did Dr. Irwin "admit" she lacked the requisite qualifications to offer her opinions. To the contrary, Dr. Irwin repeatedly and unambiguously explained that she is qualified to offer the opinions stated in her report – the clinical outcomes from the implantation of SUI devices. Notably, Plaintiffs do not challenge these qualifications.

2. Dr. Irwin is not attempting to offer "design" opinions

In their Brief [Dkt. 2008], Plaintiffs cobble together a series of non-consecutive paragraphs from Dr. Irwin's General Report and argue that she is offering "design" opinions. *See* Pls.' Br. [Dkt. 2008] at 5-8. When these paragraphs are read in context, however, it is readily apparent that Dr. Irwin is not attempting to offer "design" opinions, as that term typically connotes.

At no point do Plaintiffs define or explain what they mean by the term "design" opinions. They merely hang this label on a handful of Dr. Irwin's opinions and then claim that she cannot offer "design" opinions. Within this litigation, typically the term "design" opinions conjures thoughts of the design process, bench testing, biocompatibility testing, design selection, and theoretical design choices. But these are not the subjects upon which Dr. Irwin opines.

Instead, her opinions address the existing – not the theoretical – designs of mesh devices that are on the market. More specifically, her opinions concern the clinical response to these

existing products. She describes the physical attributes of the existing SUI products, discusses what factors she (as an expert clinician) looks for when selecting a device to treat SUI, explains how the products work, and describes how her patients and those described in the medical literature respond to the existing SUI products. These opinions are based upon her review of the medical literature and upon her 20 years of medical practice specializing in obstetrics and gynecology.

The first set of "design" paragraphs block-quoted by Plaintiffs come from a section of Dr. Irwin's General Report entitled, "HOST RESPONSE." *See* Report re: the Gynecare TVT™ Retropubic Teresa Irwin, M.D., F.A.C.O.G., F.P.M.R.S. ("Irwin General Report") [Dkt. 2006-2] at 24-30. Dr. Irwin begins by noting that the manner in which the patient responds to an implanted device will depend on a number of physical and structural properties. *Id.* at 24. Dr. Irwin then explains that "[i]n order to achieve the best host response to the reconstructive materials" four factors must be considered: the pore size of the mesh, the weave of the mesh, the weight of the mesh, and the absorption of the mesh. *Id.* at 25. Next, Dr. Irwin looks at each of these four factors and discusses the observations made in the medical literature about these factors. *Id.* at 25-27. While these discussions necessarily require a description of the physical attributes of TVT and other mesh products, Dr. Irwin is describing the clinical response of patients to these physical attributes. A patient's clinical response to medical device is well within Dr. Irwin's field of expertise.

Plaintiffs' Brief [Dkt. 2008] then jumps to page 40 of Dr. Irwin's general report, calling out a single sentence: "The design of the TVT is universally accepted by the large academic bodies: ACOG, AUGS, AUA, EUA, ICS, IUGA, NICE and SUSU." Pls.' Br. [Dkt. 2008] at 6 (quoting Irwin General Report [Dkt. 2006-2] at 40). Plaintiffs offer no explanation as to how this

constitutes a "design" opinion. True, the word "design" appears in this sentence, but the subject of the sentence is about the acceptance of TVT by all of the large academic bodies which focus on the treatment of SUI, not a particular attribute of the product's design.

Then, Plaintiffs' jump to Dr. Irwin's detailed description of the TVT design and the fact that it "makes sense to the pelvic surgeon" and to patients. Pls.' Br. [Dkt. 2008] at 6. Dr. Irwin describes in detail the device, how the product works, how the product is implanted, and how patients respond clinically to the implantation. Irwin General Report [Dkt. 2006-2] at 41-46, 49. Again, all these subjects are well within Dr. Irwin's area of expertise.

Plaintiffs attach the moniker "design" to portions of Dr. Irwin's opinions in hopes to exclude her clinical opinions. Even a cursory review of the challenged testimony reveals that Dr. Irwin is not opining on "design" issues, but rather describing the product, how it works, and its clinical results. She is imminently qualified to opine regarding these issues.

C. Dr. Irwin's opinion that mesh fraying and particle loss has no clinical significance is reliable

Dr. Irwin offers a narrow opinion on the questions of mesh fraying and particle loss. Dr. Irwin states that fraying and particle loss have not been shown to cause pain in women. Irwin General Report [Dkt. 2006-2] at 50. Specifically, she states, "this [i.e., fraying and loss of particles leading to pain] has not been shown to occur. I have not seen any literature that discusses particle loss leading to pain, nor have I seen it in my practice." *Id.* Plaintiffs argue that this opinion is unreliable. As was the case with Plaintiffs' arguments about "design" opinions, Plaintiffs again mischaracterize both Dr. Irwin's opinion and her deposition testimony in an attempt to give the illusion of unreliability.

First, Dr. Irwin does not opine that fraying or particle loss is impossible. In fact, Dr. Irwin specifically testified that fraying and particle loss can occur. Irwin 3/25/16 Dep. Tr. [Dkt. 2006-3]

at 78:11-78:20. During her deposition, Plaintiffs confronted Dr. Irwin with four documents that discuss the occurrence of fraying or particle loss, not the clinical significance of fraying or particle loss. *See* Irwin 3/25/16 Dep. Tr. [Dkt. 2006-3] at 83:14-89:24. In their Brief, Plaintiffs cite to this line of questioning and claim that Dr. Irwin was "unaware" of these documents. *See* Pls.' Br. [Dkt. 2008] at 11. But these documents have nothing to do with Dr. Irwin's opinion (i.e., that there is no peer-reviewed medical literature finding that fraying or particle loss causes pain). These four documents and Plaintiffs' citations thereto are nothing more than a red herring.

The only thing Plaintiffs point to in response to Dr. Irwin's opinion are the hearsay statements of two physicians who speculate that fraying and/or particle loss may cause pain. Pls.' Br. [Dkt. 2008] at 11. These statements go to the weight, not admissibility, of Dr. Irwin's testimony. That two surgeons have raised this topic as an object of conjecture is a subject for cross-examination, not a matter that makes her opinions fatally flawed under *Daubert*. *See Carroll v. Boston Scientific Corp.*, Civ. A. No. 2:13-cv-11601, 2016 U.S. Dist. LEXIS 60335, at *10-11 (S.D.W. Va. May 6, 2016) (expert's failure to consider document goes to weight, not admissibility, of opinion testimony).

Lastly, as Dr. Irwin aptly explained in her deposition, the hearsay statements do not change her opinion. Dr. Irwin explained that the hearsay statements upon which Plaintiffs rely do not constitute a research study and in the 17 years since those statements were first made, no research study has confirmed the hearsay statements. Irwin 3/25/16 Dep. Tr. [Dkt. 2006-3] at 82:18-83:12. Thus, her opinion stands unimpeached: there is no evidence from the medical literature or her clinical practicing demonstrations that fraying or particle loss causes pain.

D. Dr. Irwin's testimony that TVT is "state of the art" is admissible

Plaintiffs' attack on Dr. Irwin's testimony that TVT is "state of the art" is not a *Daubert* or Rule 702 issue, but rather is a question of relevance. *See* Pls' Mem. In Support of Mot. to

Exclude Certain Testimony of Teresa Irwin, M.D., *Fox v. Ethicon*, Civ. A. No. 2:12-cv-00878 ("Pls.' *Fox* Br.") [Dkt. 97] at 10-12.[1] Plaintiffs do not argue that Dr. Irwin is unqualified to offer this opinion or that Dr. Irwin failed to employ a reliable methodology in arriving at this opinion. Instead, Plaintiffs claim only that under Texas evidentiary rules, her opinion constitutes a "legal standard/conclusion" and, thus, is irrelevant. *See id.* Accordingly, this challenge should more appropriately be left to the motion *in limine* stage and should not be taken up on this *Daubert* motion. Even if it were appropriate to take up this relevance argument at this time, Dr. Irwin's opinion that TVT is "state of the art" is relevant and admissible.

Texas law does not recognize a "state of the art" defense *per se*. *Boatland of Houston, Inc. v. Bailey*, 609 S.W.2d 743, 749 n.3 (Tex. 1980).Nonetheless, the Texas Supreme Court has held expressly that evidence of "state of the art" is admissible for the purposes of a design defect claim. *Id.* at 749 & n.3. On a product liability—design defect claim, the plaintiff must prove that there exists a safer alternative design for the product. Tex. Civ. Prac. & Rem. Code § 82.005; *see also Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256 (Tex. 1999). This is a question of fact, typically left to the jury. *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 335 & n.4 (Tex. 1998). Evidence that a product is "state of the art" is relevant to the jury's determination as to the existence of a safer alternative design. *Boatland of Houston, Inc.*, 609 S.W.2d at 749.

The primary case relied upon by Plaintiffs in their Brief – *Boatland* –recognizes both the factual nature of the "state of the art" inquiry as well as the *admissibility* of such evidence. *See* Pls.' *Fox* Br. [Dkt. 97] at 11-12. *Boatland* involved a design defect claim arising from a boating

[1] Plaintiffs filed motions and briefs challenging Dr. Irwin's general opinion testimony in two separate dockets – the general MDL docket (2:12-md-02327) and the *Fox v. Ethicon* docket (2:12-cv-00878). Both motions and briefs purport to apply to the same three cases (*Barker v. Ethicon*, Civ. A. No. 2:12-cv-00899, *Quijano v. Ethicon*, Civ. A. No. 2:12-cv-00799, and *Fox*). The motions and briefs are nearly identical with the exception of the argument regarding Dr. Irwin's "state of the art" opinion. The brief filed in *Fox* covers additional points not included in the brief filed in the general MDL docket. This section of Ethicon's Response Brief addresses the *Fox* brief, which is inclusive of the arguments made in the general MDL brief.

accident. *Boatland of Houston, Inc.*, 609 S.W.2d at 745. The *Boatland* decedent was thrown from a boat when it hit a submerged tree stump. While decedent was still in the water, the boat turned and struck the decedent. *Id.* The plaintiff argued that the subject boat was defectively designed due to the fact that it was not equipped with an automatic kill switch. *Id.* The defense sought to put on evidence that kill switches were not available at the time when the subject boat was manufactured and sold. *Id.* at 747. The plaintiff put on contrary evidence. *Id.* Thus, the primary question for the jury was: what was the state of the art regarding kill switches at the time of the subject boat's manufacture.

The *Boatland* court began its design defect analysis by noting "[w]hether a product was defectively designed must be judged against the technological context existing at the time of its manufacture." *Id.* at 746. The court held:

> The state of the art with respect to a particular product refers to the technological environment at the time of its manufacture. This technological environment includes the scientific knowledge, economic feasibility, and the practicalities of implementation when the product was manufactured. Evidence of this nature is important in determining whether a safer design was feasible. The limitations imposed by the state of the art at the time of manufacture may affect the feasibility of a safer design. Evidence of the state of the art in design defect cases has been discussed and held admissible in other jurisdictions.

Id. at 748 (emphasis added). Further, the *Boatland* court held:

> Once the jury was informed of the state of the art, it was able to consider the extent to which it was feasible to incorporate an automatic cut-off device or similar design characteristic into [the subject] boat. The feasibility and effectiveness of a safer design and other factors such as utility and risk, were properly considered by the jury before it ultimately concluded that the boat sold to [the decedent] was not defectively designed.

Id. at 749 (emphasis added).

Whether TVT is a "state of the art" medical device for the treatment of SUI in women is a fact issue for the jury under Texas law, not a legal conclusion. Dr. Irwin's opinion that TVT is "state of the art" therefor is not objectionable "just because it embraces an ultimate issue" [i.e., the feasibility of a safer alternate design]. *See* Fed. R. Evid. 704. Since the feasibility of a safer alternate design is a fact issue for the jury, *see Boatland of Houston, Inc.*, 609 S.W.2d at 749, Dr. Irwin should be allowed to offer her opinion which is relevant under Rule 402 and will assist the jury in determining that fact issue.

II. CONCLUSION

For the above reasons, Ethicon and Johnson & Johnson respectfully request that this

Court enter an order denying Plaintiffs' Motion to Exclude Certain Testimony of Teresa Irwin, M.D. [Dkt. 2006].

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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